

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, the State of California, the State of Florida, the State of Hawaii, the State of Illinois, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Nevada, the State of New Mexico, the State of New York, the State of Texas, and the Commonwealth of Virginia *ex rel.* JOSEPH PIACENTILE and KEVIN B. KILCOYNE,

Plaintiffs,

v.

AMGEN INC., U.S. ONCOLOGY, INC., *et al.*,

Defendants.

No. 04-CV-3983 (SJ) (RML)

Hon. Sterling Johnson, Jr.

**RELATORS' FOURTH
AMENDED COMPLAINT
FILED PURSUANT TO 31 U.S.C.
§ 3730(b)(2)**

On behalf of the United States of America (the "United States" or "Government"), and the State of California, the State of Florida, the State of Hawaii, the State of Illinois, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Nevada, the State of New Mexico, the State of New York, the State of Texas, and the Commonwealth of Virginia (collectively the "States"), Plaintiff and Relator Joseph Piacentile, M.D. ("Dr. Piacentile") and Plaintiff and Relator Kevin B. Kilcoyne ("Mr. Kilcoyne") (collectively, "Relators") file this *qui tam* complaint against Defendant U.S. Oncology, Inc.¹ ("U.S. Oncology" or "Defendant") and allege as follows:

¹ Relators note that the only remaining defendant in this action is U.S. Oncology, Inc., as Amgen has previously resolved its potential liability. Nonetheless, Amgen remains in the case caption as the Court has not entered an order permitting or requiring amendment of the caption. Moreover, after the filing of the initial complaint in this matter, U.S.

INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States arising from false statements and false or fraudulent claims made or caused to be made by Defendant U.S. Oncology to the United States in violation of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (the “FCA”). The false or fraudulent claims and statements at issue involve payments made by federal government-funded health insurance programs for prescription drugs and medical services, including such programs as Medicaid (42 U.S.C. §§ 1396-1396w), Medicare (Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-l395kkk-l), the Federal Employees Health Benefits Program (“FEHBP”), TRICARE/CHAMPUS (10 U.S.C. §§ 1071-lllOa), Veterans Affairs Program (38 U.S.C. §§ 1701-1743), and the Railroad Retirement Medicare Program, administered under the Railroad Retirement Act of 1974, 45 U.S.C. §§ 231-231v, by the United States Railroad Retirement Board.

2. Amgen Inc. (“Amgen”) is a company which specializes in the manufacturing, marketing, and selling of prescription drugs throughout the United States. Among its many products, Amgen manufacturers and markets the oncology drugs Aranesp®, Neulasta®, and Neupogen®. Those drugs are designed to be administered in a physician’s office rather than a hospital setting, and are therefore covered by Medicare Part B of the federal government’s reimbursement regulations.² Medicare Part B covers

Oncology was acquired by McKesson Corporation. Relators reserve the right to later move to amend the case caption to include McKesson Corporation, to the extent necessary.

² In its own SEC filings, Amgen has stated that Aranesp®, Neulasta®, and Neupogen® are Medicare Part B drugs. (*See* Amgen February 28, 2007 10K, available at <http://investors.amgen.com/phoenix.zhtml?c=61656&p=irol->

physician administered drugs in an outpatient setting, and covered the Amgen oncology drugs at issue in this matter for all relevant times.³

3. One of the principal purchasers of Aranesp®, Neulasta®, and Neupogen® is the federal government, primarily through its Medicaid and Medicare programs. In 2008, Amgen generated revenues of approximately \$15 billion.

4. Alternative oncology drugs made by competing pharmaceutical companies were available during all times relevant to this complaint. Those competitor drugs were capable of delivering results for cancer patients similar to those provided by Amgen's drugs. Because of the existence of serious competitors in the oncology sector, Amgen was incentivized to use illegal means to persuade physicians to use its oncology drugs.

5. Between 2001 and 2011, Amgen attempted to persuade oncology groups—specifically targeting large oncology networks that controlled numerous physicians—to prescribe its oncology drugs. In so doing, Amgen used a variety of methods to provide illegal incentives to oncology groups and physicians, including but not limited to paying kickbacks to these groups and physicians to incentivize them to use Amgen's drugs.

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³ Medicare Part B generally does not cover prescription drugs used at home. It does, however, cover a limited number of outpatient prescription drugs under limited conditions. Generally, drugs covered under Part B are drugs a patient would not administer himself. These include drugs administered by a physician in an office or hospital outpatient setting.

6. As described in further detail below, these kickbacks violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (“AKS”), the FCA, the Medicaid Best Price Statute (42 U.S.C. §1396r-8), and various state false claims acts.

7. Amgen, as part of its conspiracy with these oncology networks, ensured that the kickbacks were kept secret from and not reported to the Government or the States by Amgen or by its co-conspirator oncology networks.

8. Since Amgen’s kickbacks to purchasing physicians and oncology networks brought the actual price of Amgen’s drugs below the “Best Price”⁴ reported by Amgen to the Government, had Amgen’s kickback scheme been known by the Government, Amgen would have been required to pay hundreds-of-millions-of-dollars in rebates to the Government pursuant to the Medicaid Best Price Statute for improper payments made by the Government in excess of Amgen’s actual “Best Price.”

9. Between 2004 and 2011, various whistleblowers—including Relator Piacentile—filed FCA lawsuits against Amgen and others for this alleged conduct.

10. Relator Piacentile’s 2004 complaint was the second FCA complaint filed against Amgen in this time period, but the first to address Amgen’s illegal kickbacks to oncology networks and physicians, and focused on the various kickbacks that Amgen employed to induce physicians to prescribe its drugs.

⁴ “Best Price” means the lowest price at which the pharmaceutical company sells its drug to retail, for-profit customers, such as private insurers, wholesalers, pharmacists, group purchasing organizations, and other similar businesses. In order to induce these private insurers, pharmacists, and businesses to purchase their drugs, pharmaceutical companies may offer their drugs at prices below the “Best Price” offered to Medicaid. In order to avoid violating the law, pharmaceutical companies must provide a rebate to the Government—the difference between the price they initially charged Medicaid and their “Best Price”—each year to account for the difference in pricing.

11. One of the defendants in Relator Piacentile's 2004 complaint was U.S. Oncology, and various allegations were made regarding Amgen's use of kickbacks to induce U.S. Oncology and its physicians to prescribe Amgen's drugs.

12. Another defendant in that case was Amerisource Bergen, who engaged in similar conduct as alleged herein. Amerisource Bergen recently resolved its FCA liability to the Government in a \$625 million settlement announced on October 1, 2018.⁵

13. Relator Kilcoyne later joined Relator Piacentile's FCA lawsuit, and the 2004 complaint was amended accordingly. Relator Kilcoyne, a former award-winning Amgen pharmaceutical sales representative who serviced the Greater Worcester/Boston area of Massachusetts, personally delivered Amgen kickback checks to physicians at U.S. Oncology locations in his sales area, thereby adding direct and personal knowledge of Amgen's illicit activities to Relator Piacentile's complaint.

14. After Relators' complaint had been under seal and part of an ongoing Government investigation for approximately eight years, in 2012 the Government entered into a global settlement agreement with Amgen, in which Amgen agreed to pay \$762 million to resolve its criminal liability and all pending FCA allegations—with \$612 million (\$587.2 million to the United States and \$24.8 million to the States) being paid to resolve the FCA suits and \$150 million being paid for criminal penalties and forfeiture.

(See DOJ Press Release dated December 19, 2012, *available at* <https://www.justice.gov/opa/pr/amgen-inc-pleads-guilty-federal-charge-brooklyn-ny-pays-762-million-resolve-criminal>).

⁵ Relators Piacentile and Kilcoyne were not included in that settlement, as they previously voluntarily dismissed their claims against Amerisource Bergen.

15. The civil settlement agreement encompassed allegations that Amgen: (1) promoted Aranesp and two other drugs that it manufactured, Enbrel and Neulasta, for off-label uses and doses that were not approved by the FDA and not properly reimbursable by federal insurance programs; (2) offered illegal kickbacks to a wide range of entities in an effort to influence health care providers to select its products for use, regardless of whether they were reimbursable by federal health care programs or medically necessary; and (3) engaged in false price reporting practices involving several of its drugs. As part of the global settlement, Amgen also agreed to enter into a Corporate Integrity Agreement (CIA) with HHS-OIG that would govern its conduct, and ensure oversight of its branding and marketing practices.⁶

16. Thus, Amgen paid \$762 million to the Government and the States for precisely the conduct that Relators Piacentile and Kilcoyne alleged in their complaint, *i.e.* that Amgen employed a variety of illegal methods to pay kickbacks to purchasing organizations and networks that were not reported to the Government, including oncology networks, to induce those physicians to purchase and prescribe Amgen's drugs.

⁶ Specifically, the 2012 global settlement agreement states that Amgen offered or paid, or caused to be paid directly and indirectly through Amerisource Bergen Specialty Group, Amerisource Bergen Corp., Cardinal Health Specialty Pharmaceutical Distribution, International Nephrology Network, International Oncology Network, Onmark, National Oncology Alliance, Oncology Supply, Inc., and Oncology Therapeutics, Inc., to health care providers, including, physicians, pharmacists, physician organizations, hospitals, managed care organizations, and group purchasing organizations and physician practice management organizations, remuneration, specifically in the form of cash, free product, free samples, product overfill, dinners, travel, hotels, consulting fees, education research grants, free consulting services, free reimbursement support services to assist physicians to secure coverage for Amgen products, improper remuneration disguised as proper discounts and rebates, improperly bundled products, payments for phony data collection studies and information collection programs, honoraria and speaker fees, for the purpose of influencing health care providers' selection and utilization of Aranesp, Enbrel, Epopen, Neulasta, Neupogen, and Sensipar regardless of whether the product was administered, reimbursable by federal health care programs, or medically necessary.

17. While the 2012 global settlement resolved all FCA claims against Amgen, it did not cover Amgen's conduct vis-à-vis U.S. Oncology, as only Relators Piacentile and Kilcoyne had asserted claims against that particular purchasing organization.

18. Thus, the 2012 global settlement between the Government and Amgen did not settle Relators' allegations as to Defendant U.S. Oncology. While Amgen was released from further liability for the covered conduct set forth in the 2012 settlement, U.S. Oncology was not and Relators' claims against U.S. Oncology were preserved.

19. By way of this Fourth Amended Complaint, Relators Piacentile and Kilcoyne now seek to recover for U.S. taxpayers the funds that are the subject of U.S. Oncology's fraud, and address U.S. Oncology's liability for those funds for the first time.

20. This is also an action to recover double and treble damages and civil penalties on behalf of the named States arising from the conduct of Defendant U.S. Oncology who: (a) made, used or presented, or caused to be made, used or presented, certain false or fraudulent statements, records and/or claims for payment or approval to the States; and/or (b) made, used or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the States, all in violation of each State's respective false claims act or similar statute. The false or fraudulent claims, statements and records at issue involve payments made by health insurance programs funded by these State governments, including Medicaid.

21. The statutes of the States under which Relators bring these related actions are the:

- a. California False Claims Act, Cal. Govt. Code §§ 12651 *et seq.*;
- b. Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq.*;

- c. Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*;
- d. Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*;
- e. Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:439.1 *et seq.*;
- f. Massachusetts False Claims Law, Mass. Gen. Laws ch. 12, §§ 5A *et seq.*;
- g. Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.*;
- h. Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*;
- i. New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 *et seq.*, and New Mexico Fraud Against Tax Payers Act, N.M. Stat. Ann. §§ 44-9-1 *et seq.*;
- j. New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq.*;
- k. Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.002; and
- l. Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*.

DAMAGES CAUSED BY THE UNLAWFUL KICKBACK SCHEME

22. As a result of its unlawful conspiracy with Amgen, Defendant U.S. Oncology facilitated and caused false, fraudulent and improper billings to be submitted to the Government and the States, inducing Medicare, Medicaid and other federal and state government-funded health insurance programs, to pay hundreds-of-millions-of-dollars in inflated reimbursements to undeserving physicians at taxpayer expense, while the companies skirted the rebate requirements of the Medicaid Best Price Statute and flouted the anti-kickback provisions of the AKS.

23. As a result, the federal and state governments have paid enormous sums for claims they would have otherwise refused to pay had they been aware of U.S. Oncology's illegal scheme with Amgen resulting in increased prescription drug costs to the federal and state governments. As Amgen's co-conspirator, and as an entity that negotiated for and accepted these illegal kickbacks, U.S. Oncology earned enormous profits as a result of its scheme.

24. In addition to the unnecessary expenses the Government and the States have paid as a result of this fraud, cancer patients have borne the reality that U.S. Oncology and its affiliated physicians made decisions related to treatment not based on which oncology drugs provided their patients with the best results, but rather which drugs offered the best opportunity for financial gain.

JURISDICTION AND VENUE

25. This Court has jurisdiction over the subject matter of this action pursuant to 31 U.S.C. § 3729, *et seq.*, and 28 U.S.C. § 1331 because this action arises under the laws of the United States, in particular the federal FCA.

26. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and Defendant has sufficient minimum contacts with the United States.

27. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because acts complained of herein occurred in the State of New York within this judicial district and U.S. Oncology transacts business within the Eastern District of New York.

28. In accordance with the Court's September 17, 2018 Order (Dkt. No. 167), this Fourth Amended Complaint has been publicly filed and shall be served on the Defendant.

29. Pursuant to 31 U.S.C. § 3730(b)(2), the Relators must provide the Government with a copy of the Fourth Amended Complaint and/or a written disclosure of substantially all material evidence and material information in their possession contemporaneous with the filing of the Fourth Amended Complaint. Relators have complied with this provision by serving copies of this Fourth Amended Complaint on Richard P. Donoghue, United States Attorney for the Eastern District of New York, and the Honorable Matthew G. Whitaker, Acting Attorney General of the United States. Relators have also previously provided substantially all material evidence and documents in their possession to the Government and have since provided additional information that they have obtained in supplemental disclosures.

30. With the exception of the lifting of the seal in this matter, Relators are not aware that the allegations in this Fourth Amended Complaint against U.S. Oncology have been publicly disclosed. Further, to the extent Relators are aware of any public disclosures, this Fourth Amended Complaint is not based on such public disclosures. In any event, this Court has jurisdiction under 31 U.S.C. § 3730(e)(4) because the Relators are an "original source" of the information herein, given that they have provided their information voluntarily to the Government before filing their original complaint, and have knowledge that is both direct and independent of any public disclosures to the extent any exist.

THE PARTIES

31. Co-Relator Joseph Piacentile, M.D., resides in the State of New Jersey and is a licensed, non-practicing physician engaged in the healthcare industry. Dr. Piacentile has personal knowledge of U.S. Oncology's practices as a result of an extensive undercover investigation he personally conducted in which he secured admissions from top executives of Amgen and U.S. Oncology regarding the allegations set forth herein. This investigation was conducted at a time when none of the alleged conduct had been publicly disclosed.

32. Co-Relator Kevin B. Kilcoyne resides in the Commonwealth of Massachusetts and was employed by Amgen as a Professional Sales Representative for close to fifteen years, from September 1990 through May 2005. Mr. Kilcoyne's sales territory included the Greater Worcester/Boston, Massachusetts area. During this employment, Mr. Kilcoyne received numerous awards from Amgen, including multiple Amgen "Impact Awards" for sales quota attainment, increased hospital share, and high client conversion percentages. In 2003, Mr. Kilcoyne ranked third nationally in sales of Amgen's prescription drug Neulasta, attained 255% of his sales quota, and earned a Neulasta Extreme Team Award. From this employment, Mr. Kilcoyne gained direct and personal knowledge of the facts alleged herein.

33. Defendant U.S. Oncology was a corporation incorporated in Delaware and headquartered in Houston, Texas. At the time of the filing of the initial complaint, U.S. Oncology had cancer treatment centers in 39 states and was composed of over 1,200 physicians who cared for more than 640,000 patients a year. On information and belief,

U.S. Oncology billed Medicare and Medicaid for Amgen pharmaceuticals at a rate of more than \$60 million a year.

34. In December 2010, U.S. Oncology was acquired by McKesson Corporation in a transaction valued at \$2.2 billion. The Company presently maintains a headquarters at 10101 Woodloch Forest, The Woodlands, Texas 77380.

35. Former defendant and U.S. Oncology's co-conspirator Amgen is incorporated in Delaware and headquartered in Thousand Oaks, California. Amgen is in the business of manufacturing, marketing, and selling prescription drugs throughout the United States. Among its many products, Amgen manufacturers and markets the oncology drugs Aranesp®, Neulasta®, and Neupogen®. One of the principal purchasers of Aranesp®, Neulasta®, and Neupogen® is the federal government, through its Medicaid and Medicare programs. In 2008, Amgen generated revenues of approximately \$15 billion.

36. Amgen is no longer a party in this case, but because its contracts with U.S. Oncology form the basis of the violations asserted, Amgen's conduct is relevant to the violations alleged against Defendant U.S. Oncology.

SPECIFIC ALLEGATIONS

37. This matter involves kickbacks in various forms paid by Amgen to Defendant U.S. Oncology to induce U.S. Oncology's physicians to prescribe Amgen's drugs Aranesp®, Neulasta®, and Neupogen® and use them to treat their cancer patients.

38. Specifically, U.S. Oncology solicited and received from Amgen kickbacks and other illegal benefits in the form of rebate checks issued to practices and individual physicians, pricing discounts, inflated data fees, free practice management services, travel

offers and sham speaker fees. All of these monetary benefits, which were specifically bargained for by U.S. Oncology and resulted in significant profits for U.S. Oncology, went unreported to the Government. As a result, U.S. Oncology's and Amgen's illicit arrangement violated the Government's "Best Price" statute, rules and regulations, defrauding the Government out of hundreds-of-millions-of-dollars.

39. The purpose of this conspiracy to defraud the Government was simple. From Amgen's perspective, it was to win market share from competing oncology drugs that were as effective (if not more effective) than Amgen's products. For U.S. Oncology, the scheme was to drive down the cost of its drug supply as low as possible so as to profit from the "spread" between the price U.S. Oncology was paying for Amgen's drugs, and the inflated amount it was being reimbursed for these drugs by the Government.

40. Amgen and U.S. Oncology and its physicians agreed to keep confidential and not report to the Government the numerous secret discounts, rebates, and other kickbacks that Amgen was providing to U.S. Oncology and its physicians and did not disclose those kickbacks either in Amgen's reports filed with the Government, or in claims forms submitted by U.S. Oncology and its physicians to the Government for reimbursement under Medicare or Medicaid for physician-administered pharmaceuticals purchased from Amgen.

41. As discussed in further detail below, a U.S. Oncology employee outright admitted to Relator Piacentile that U.S. Oncology knew that the Amgen/U.S. Oncology conspiracy was violating best price. The employee said that "**we do dip below [best price] every now and then and what happens if they catch us then they . . . will have**

to go back and pay back the government[.]" The employee indicated that it was "worth the chance" and that having to make back-payments was "no big deal[.]"

42. Furthermore, Relator Kilcoyne personally delivered Amgen kickback checks to three U.S. Oncology locations in Massachusetts.

43. Had the Government been aware of U.S. Oncology's and Amgen's conspiracy to violate the Government's "Best-Price" statute, rules and regulations, it would have sought restitution of ill-gotten gains and reduced any future reimbursement payments to U.S. Oncology during all times relevant to this scheme.

44. Dr. Piacentile's and Mr. Kilcoyne's knowledge set forth herein was gained from:

- i. Dr. Piacentile's undercover investigation of Amgen and U.S. Oncology, where he interviewed and audio-taped employees of Amgen, U.S. Oncology, and other companies, who described the details of the scheme from both Amgen and U.S. Oncology's perspective, and gave specific examples of the conduct and individuals involved.
- ii. Mr. Kilcoyne is able to confirm, through direct and personal knowledge of Amgen's operations as a former Amgen sales representative who serviced U.S. Oncology practices, much of the information gleaned through Dr. Piacentile's investigation.

45. Together, Dr. Piacentile and Mr. Kilcoyne present a detailed and compelling picture of Amgen and U.S. Oncology's scheme to defraud the United States and the States.

46. The conduct that Amgen and U.S. Oncology engaged in from 2001 through 2011 violated both the federal civil and criminal Anti-Kickback Statute, the Medicaid Best Price Statute (which requires, among other things, that pharmaceutical companies report to the Government the best price they have provided to any drug purchaser during each quarter), the FCA, and the state false claims acts.

47. Dr. Piacentile and Mr. Kilcoyne bring this action for violations of the FCA on behalf of themselves and the United States of America and on behalf of the named States under each states' version of the FCA.

A. U.S. Oncology

48. For all times relevant to this complaint, U.S. Oncology was a complex entity with varied involvement in the medical and pharmaceutical industry. While U.S. Oncology held itself out as one of the nation's largest cancer treatment and research "networks," in reality, it was much more.

(<https://www.sec.gov/Archives/edgar/data/943061/000119312510250320/d10q.htm>).

49. U.S. Oncology's network physicians, to whom Amgen provided illegal remuneration and kickbacks, prescribed large volumes of Amgen drugs to Medicaid and Medicare patients and beneficiaries of other government healthcare programs in violation of federal and state laws.

50. U.S. Oncology, which conducts all billing for its network physicians, in turn submitted claims to Medicaid, Medicare and other government healthcare programs and obtained hundreds of millions of dollars worth of payments from the United States and the named States.

51. Under the FCA and related state false claims acts, such claims were fraudulent because they sought reimbursement for Amgen drugs at rates significantly above the levels the network physicians would receive had they disclosed the kickbacks and price discounts they received from Amgen to the federal and state governments.

52. U.S. Oncology advertised itself as owning or managing affiliated oncology practices across the country. The mechanics of those arrangements are relevant to this complaint.

53. Services U.S. Oncology offered to its network physicians included (i) drug contracting and drug distribution services, (ii) drug management services such as supporting inventory management, drug charge capture, and analysis of chemotherapy regimens, (iii) revenue cycle tools and information such as billing and coding courses for practice staff, patient assistance support resources and web-based applications to better manage denials and reduce practice bad debt, and (iv) clinical and nursing tools.

54. U.S. Oncology offered various service structures. Under the model known as a “comprehensive strategic alliance,” U.S. Oncology would “own or lease all of the real and personal property used by [an] affiliated practice[]. In addition, [U.S. Oncology] generally manage[s] the non-medical business operations of [its] affiliated practices and facilitate[s] communication with [its] affiliated physicians.”

55. For these practices, U.S. Oncology was “responsible for non-medical decisions, including facilities management and information systems management[,]” and “account[s] for all expenses that [it] incur[s] in connection with managing a practice, including . . . pharmaceutical expenses, and salaries and benefits of non-physician employees of the practices, and [U.S. Oncology is] paid a management fee based on a

percentage of the practice's earnings before income taxes, subject to certain adjustments."

56. Another of U.S. Oncology's service models, the "Targeted Physician Services" model, offered targeted arrangements where a subset of the services offered through comprehensive management agreements were provided separately to oncologists on a fee-for-service basis.

57. Targeted physician services represented 17.7% and 15.5% of U.S. Oncology revenue during the nine months ending September 30, 2010 and 2009, respectively, which was primarily fees for payment for pharmaceuticals and supplies used by the practice and reimbursement for certain pharmacy-related expenses. A smaller portion of revenue came from targeted arrangements and payment for the other services U.S. Oncology provides.

58. As of 2004, U.S. Oncology directly owned and operated 477 oncology practices that included more than 850 physicians. According to Cynthia Radford, Director of Business Development for U.S. Oncology from 2002 to at least 2004 (who Relator Piacentile interviewed in 2004), U.S. Oncology controlled nearly all aspects of these practices.

59. As of 2004, U.S. Oncology also owned and operated 77 free-standing comprehensive cancer centers, which provided chemotherapy treatment and other services. U.S. Oncology began operating these facilities to help diversify its portfolio and insulate against a decrease in profits from its drug sales and distribution.

60. U.S. Oncology made most of its revenue by negotiating market volume-purchase, market share, or use-based rebate and discount contracts with pharmaceutical

companies (like Amgen) and then directing its affiliated practices to purchase and prescribe the drugs it had contracted for.

61. In addition to oncology practices, U.S. Oncology's website indicates that it now has in its network 84 comprehensive cancer centers and 15 facilities providing radiation therapy only and a research network currently managing 97 active clinical trials. U.S. Oncology also directly owns many, if not all, of these facilities.

B. Amgen

62. Amgen markets and manufactures darbepoetin alfa, a protein that stimulates bone marrow cells to increase red blood cell production, under the trade name Aranesp®. The FDA has approved Aranesp® for the treatment of anemia associated with chronic renal failure, including patients on dialysis, and for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. Aranesp® is administered by injection, and dosing regimens vary depending on the specific indications described in the package insert for the drug.

63. Amgen manufactures another protein, epotein alfa, that the FDA has approved for use in nearly identical indications. Amgen sold the rights to market epotein alfa to Ortho Biotech Products, Inc., who markets the drug under the trade name Procrit®. Procrit® and Aranesp® compete directly for the same pool of patients who require increased blood cell production in order to combat anemia resulting from chronic renal failure or chemotherapy in connection with non-myeloid malignancies. The Aranesp® product insert describes how physicians can convert patients from Procrit® to Aranesp®.

64. Filgrastim is a human granulocyte colony stimulating factor (G-CSF), produced by recombinant DNA technology, which Amgen manufactures and markets under the trade name Neupogen®. The FDA has approved Neupogen® for use by patients receiving myelosuppressive anti-cancer drugs to fight non-myeloid malignancies. Neupogen® reduces the incidence of infection, manifested by febrile neutropenia, in these patients, by stimulating the production of white blood cells.

65. Pegfilgrastim, another G-CSF that Amgen markets under the trade name Neulasta®, is also FDA-approved as a treatment to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta® is an alternative treatment to Neupogen®.

66. As described earlier, in December 2012, Amgen entered into a settlement agreement with the Government resolving various alleged conduct involving its payment of kickbacks and remunerations to the oncology industry. This settlement did not include or resolve U.S. Oncology's potential liability for its receipt of kickbacks from Amgen, as is alleged in this Fourth Amended Complaint.

67. According to the 2012 settlement agreement between Amgen, the United States and various state governments and relators, from January 1, 2001, to September 30, 2011, in violation of the AKS and/or the FCA, Amgen offered or paid, or caused to be paid directly and indirectly through Amerisource Bergen Specialty Group, Amerisource Bergen Corp., Cardinal Health Specialty Pharmaceutical Distribution, International Nephrology Network, International Oncology Network, Onmark, National Oncology Alliance, Oncology Supply, Inc., and Oncology Therapeutics, Inc., to health

care providers, including, physicians, pharmacists, physician organizations, hospitals, managed care organizations, and group purchasing organizations and physician practice management organizations, remuneration.

68. This remuneration specifically came in the form of cash, free product, free samples, product overfill, dinners, travel, hotels, consulting fees, education, research grants, free consulting services, free reimbursement support services to assist physicians to secure coverage for Amgen products, improper remuneration disguised as proper discounts and rebates, improperly bundled products, payments for phony data collection studies and information collection programs, honoraria and speaker fees, for the purpose of influencing health care providers' selection and utilization of Aranesp®, Enbrel®, EpoGen®, Neulasta®, Neupogen®, and Sensipar® regardless of whether the product was administered, reimbursable by federal health care programs, or medically necessary.

69. According to the 2012 settlement, from April 30, 2004, to January 1, 2008, Amgen knowingly reported inaccurate Average Sales Prices ("ASP") for Aranesp®, EpoGen®, Neulasta®, and Neupogen® by failing to account properly for price concessions, including group purchasing organization volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, and price concessions disguised as *bona fide* service fees, in the calculation of ASP. Amgen employees and agents were directed to explain the profitability of the inaccurate ASP.

70. From April 30, 2004, to September 30, 2011, Amgen knowingly reported inaccurate ASP for Aranesp®, EpoGen®, Neulasta®, and Neupogen® by failing to account properly for price concessions including rebates, volume discounts and free

goods that were contingent on any purchase requirement, referred to in the settled complaints as “bundled pricing[.]” Amgen employees and agents were directed to explain the profitability of the inaccurate ASP.

71. During the period from January 1, 2001, to September 30, 2011, Amgen knowingly reported inaccurate Best Prices and Average Manufacturer Prices for Aranesp®, Enbrel®, Epopen®, Neulasta®, Neupogen® and Sensipar® by failing to include remuneration that was paid to health care providers and that was conditioned on purchase of Amgen products in violation of the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8.

C. An Overview of Amgen/U.S. Oncology’s Unlawful Kickback and Related Best Price Conspiracy

72. In or about February 28, 2002, Amgen entered into a multi-year agreement with U.S. Oncology to provide Aranesp®, Neulasta® and Neupogen®. This contract was worth approximately \$250 million per year.

73. As part of his investigation, Dr. Piacentile interviewed Anthony Corrao, a former Amgen sales executive, who managed the negotiations with U.S. Oncology that resulted in the 2002 agreement.

74. During these negotiations, U.S. Oncology demanded from Amgen unlawful financial incentives that included Amgen paying grants, giving drug price discounts and rebates, and sponsoring physician speakers, advisory boards and conferences, all to U.S. Oncology or for the benefit of its physician members. These incentives would illicitly compensate U.S. Oncology for referring its physician members to prescribe and/or use Amgen drugs and would compensate the physician members for prescribing and/or using Amgen drugs.

75. U.S. Oncology made clear that, in order to get the contract and U.S. Oncology's business, Amgen would have to provide incentives that exceeded those provided by U.S. Oncology's then-current supplier of competing drugs.

76. Amgen agreed to provide these illegal incentives, and U.S. Oncology entered into the multi-year agreement.

77. Dr. Piacentile also interviewed Michael Louviere, Vice President of Marketing for U.S. Oncology, who had been directly and significantly involved in the negotiations of the Amgen agreement with Mr. Corrao.

78. Under the agreement, U.S. Oncology acted as the gateway that allowed its network physicians to glean profits from Amgen's price discounts and kickbacks while illegally benefiting itself.

79. When Amgen struggled to launch Aranesp, U.S. Oncology used its clout to help Amgen push the product in exchange for kickbacks. U.S. Oncology agreed to help Amgen get Aranesp on the continuum by directing its physicians to prescribe the drug. As Mr. Louviere put it, "having 900 physicians in [U.S. Oncology's] back pocket" made it easy to run such a scheme. U.S. Oncology viewed the process of forcing its physicians into compliance with its directive to use Aranesp as simply "herding cats[.]"

80. In particular, U.S. Oncology handled all of its networks physicians' accounting and billing to Government funded health insurance programs and routinely escalated the reimbursement rate for the drugs it purchased from Amgen.

81. U.S. Oncology had regional billing centers that handled all billing. One center was located in the Carolinas, and one was located in Houston, Texas.

82. According to U.S. Oncology's Louviere, U.S. Oncology made it a practice to never report kickbacks or price discounts received from Amgen to the Government.

83. Defendant U.S. Oncology was thereafter one of Amgen's major customers, and actively participated in violating the AKS, the Medicaid Rebate Statute and the FCA. Amgen paid kickbacks and illegal remuneration to U.S. Oncology and its physicians in order to induce U.S. Oncology and its physicians to prescribe Amgen drugs including Aranesp®, Neulasta® and Neupogen®, rather than competing drugs.

84. The kickbacks Amgen paid to prescribing U.S. Oncology physicians came in many forms, including cash payments, so-called "research grants," free services, free equipment, drug price discounts and other inducements.

85. By soliciting and receiving illegal kickbacks and price discounts from Amgen which were not disclosed to the Government in violation of the AKS and the Medicaid Rebate Statute, U.S. Oncology improperly sought reimbursement for Amgen drugs from Government-funded health insurance programs, and filed false and/or fraudulent certifications regarding compliance with the AKS and the Medicaid Rebate Statute in violation of the FCA.

86. To conceal its unlawful conduct and avoid refunding payments made on false claims, U.S. Oncology falsely certified, in violation of the FCA, that the claims it submitted or caused to be submitted to the Government were made in compliance with federal law, including the prohibitions against kickbacks and illegal remuneration to physicians.

87. By illegally soliciting and accepting kickbacks in exchange for prescribing Amgen drugs, U.S. Oncology's actions have illegally moved market share to specific

drugs by inducing physicians to prescribe medications they would not have otherwise prescribed but for the receipt of kickbacks and price discounts.

88. Moreover, by intentionally concealing both the payment of kickbacks and price discounts from Amgen to U.S. Oncology, and from U.S. Oncology to its member-physicians and its stand-alone cancer treatment centers, Amgen failed to accurately report the “best price” of Medicaid covered drugs as required by the Medicaid Rebate Statute, 42 U.S.C. §1396r-8. This has resulted in millions of dollars of overpayments by both the federal government and State governments in Medicaid payments to U.S. Oncology.

89. Before the Court is the first and only complaint to ever address U.S. Oncology’s fraudulent scheme with Amgen.

90. The Relators’ investigation uncovered specific and uncontroverted evidence of Amgen’s payment of kickbacks to U.S. Oncology and its network physicians in order to increase its market share. Below are some specific examples.

i. Unlawful Rebate Checks and Pricing Discounts

91. Dr. Piacentile interviewed Cynthia Radford, Director of Business Development for U.S. Oncology from 2002 to at least 2004, who stated that U.S. Oncology would contract with pharmaceutical companies for kickbacks, the pharmaceutical companies would provide “rebates” to U.S. Oncology (along with additional remuneration), and U.S. Oncology would pass some of those rebates along to its physicians while retaining some for itself as profit.

92. Additionally, pharmaceutical company representatives would visit the individual U.S. Oncology practices to provide additional, direct “incentives” to the U.S. Oncology physicians to help promote their products.

93. As a result of the contract between Amgen and U.S. Oncology, a U.S. Oncology network physician was typically able to glean \$300,000 per quarter from Amgen discounts and incentives by paying a \$44,000 monthly fee to U.S. Oncology. These “incentives” were never reported to the Government, which resulted in inflated reimbursements from Government insurers to U.S. Oncology, thereby violating the “best price” rules and regulations.

94. U.S. Oncology provided its network physicians with a Quarterly Business Review, which detailed the kickback checks they were due to receive from pharmaceutical companies.

95. The purpose of the Quarterly Business Review was to encourage U.S. Oncology network physicians to increase their prescriptions of drugs that provided rebates—*i.e.* to work with those companies (like Amgen) that agreed to provide U.S. Oncology with illegal pricing benefits. In fact, Amgen instructed its sales representatives to use the Business Review as a “contract selling tool[.]” *See* Amgen PowerPoint Presentation Slide, attached hereto as Exhibit A.

96. In order to ensure its success in negotiating these use-based contracts and in actually meeting its required use, U.S. Oncology convinced or directed hundreds of physicians to join its scheme and use the preferred pharmaceuticals it was making money on. To guarantee its use-base metrics were satisfied, U.S. Oncology would push preferred formulary drugs to its physicians over less incentivized drugs.

97. For example, in or about 1994, U.S. Oncology negotiated with Amgen for a contract whereby U.S. Oncology committed to purchase a certain amount of Amgen’s Aranesp® in exchange for certain kickbacks.

98. Per Ms. Radford, the Amgen-U.S. Oncology agreements were negotiated by U.S. Oncology's purchasing department. Specifically, for the Amgen agreement, U.S. Oncology's Brian Manning, Vice President of Purchasing, handled the negotiations. Mr. Manning reported to Corey Stevenson, who also knew of the deal.

99. Moreover, U.S. Oncology had similar contracts with other pharmaceutical companies, including Aventis for Anzemet® and Novartis for Iridium.

100. Per Ms. Radford, those types of contracts persisted until at least 2004.

101. U.S. Oncology used its group purchasing power to "shake down" the manufacturers for kickbacks. Ms. Radford noted that U.S. Oncology would ask its suppliers to "bend the rules" for it, because it had what the pharmaceutical companies needed: "access to patients" and "real practices" that could move large amounts of product.

102. Pharmaceutical companies were unhappy with U.S. Oncology's demands, but nonetheless participated because U.S. Oncology had a captured audience with a large group of prescribers and available patients.

103. In exchange for that commitment, Amgen offered to U.S. Oncology a kickback that Amgen categorized as both discounts and rebates.

104. U.S. Oncology knew that these contract negotiations meant large sums of rebate, discount, and kickback monies for both it and its affiliated practices.

105. For the practices affiliated with U.S. Oncology, these agreements meant the practices would save money on drugs purchased, but they had to pay U.S. Oncology a fee for that purchasing right.

106. U.S. Oncology's Louviere explained the process as such: a pharmaceutical company would sell its product to the general purchaser for \$100. U.S. Oncology would come in and refuse to pay anything over \$92. Once U.S. Oncology convinced the company to sell it to them at the discounted rate, it would then charge its practices \$98 for the same drug, giving the practice a slight discount, while U.S. Oncology kept substantial profits. When asked whether U.S. Oncology treated this as a discount or a rebate, U.S. Oncology's Louviere responded that "you could call it anything you want" because U.S. Oncology is "very creative in how [it] do[es] it." U.S. Oncology called its scheme a "game."

107. The "game" was really a conspiracy. U.S. Oncology and Amgen conspired to discount prices below "best price" so that U.S. Oncology could increase profits while Amgen would increase its market share, product usage, and profits. By engaging in this kickback conspiracy, U.S. Oncology received a windfall from Amgen, as it received both reimbursement from the Government for the Amgen products it used, in an amount unlawfully inflated by Amgen's and U.S. Oncology's non-disclosure of the kickbacks paid, and also received financial benefits by way of those kickbacks, which caused the effective price U.S. Oncology was paying for Amgen products to fall substantially below best price.

108. In fact, for affiliated practices not directly owned by U.S. Oncology, in order to gain access to the U.S. Oncology purchasing contracts, practices had to pay between \$40,000 and \$70,000 per month. In exchange for this payment to U.S. Oncology, affiliated practices would receive access to discounted Amgen products.

109. Amgen would also offer kickbacks to physicians at U.S. Oncology owned and managed practices beyond what it provided to U.S. Oncology directly. These physician-direct rebates were tethered directly to the amount of Aranesp® purchased by that particular physician.

110. U.S. Oncology practices would also receive “added fees” from Amgen that increased the kickbacks received by the practices.

111. The physician-direct rebates came directly from Amgen to the practice by way of a check, often delivered by Amgen pharmaceutical representatives on a quarterly basis. As described in greater detail below, Relator Kilcoyne (an Amgen pharmaceutical representative) personally delivered many of these checks to three Massachusetts-based U.S. Oncology practices in the Greater Worcester/Boston area.

112. The Amgen discounts paid directly to the practices were often large. For example, Ms. Radford noted that in 2004, a U.S. Oncology practice in Morristown, New Jersey, was set to receive a \$500,000 “rebate” check from Amgen for its use of Aranesp®.

113. Relator Kilcoyne himself recalls delivering Amgen rebate checks worth several hundred thousand dollars to U.S. Oncology practices in his sales area.

114. Specifically, Relator Kilcoyne was responsible for servicing U.S. Oncology practices in Pittsfield, Massachusetts, North Adams, Massachusetts, and Great Barrington, Massachusetts; all of which were affiliated with the Berkshire Hematology Oncology group.

115. Relator Kilcoyne regularly called on the physicians and nurses at the Pittsfield, North Adams, and Great Barrington locations, including Michael J. DeLeo,

M.D., Paul Rosenthal, M.D., Jesse I. Spector, M.D., Spyridon Triantos, M.D., and Harvey Zimbler, M.D. Relator Kilcoyne also routinely met with nurse Pamela S. Doyle, N.P. and office manager Fred Harrison, who managed all of the U.S. Oncology purchases for these locations.

116. In fact, Relator Kilcoyne's calendar entries indicate that he met with U.S. Oncology/Berkshire Hematology Oncology routinely from 2002 through 2005, visiting the Pittsfield, North Adams, and Great Barrington locations more than forty (40) times from June 2002 through November 2004.

117. For example, at 11:30 a.m. on January 26, 2004, Relator Kilcoyne visited the Pittsfield U.S. Oncology location to deliver information and remuneration relevant to U.S. Oncology's "Reimbursement Program[.]" *See Exhibit B attached hereto.*

118. By way of further example, the itinerary Relator Kilcoyne kept during his time as an Amgen sales representative shows that he met with various U.S. Oncology representatives between noon and 1:30 p.m. on November 30, 2004. Relator Kilcoyne met with Dr. Rosenthal and staff nurses Julie, Linda and Gloria to discuss Neulasta and Aranesp. *See Exhibit C attached hereto.* Relator Kilcoyne provided the same information to other U.S. Oncology physicians, nurses, and business administrators throughout that same day. Relator Kilcoyne's calendar shows similar meetings occurring through May 2005.

119. Relator Kilcoyne's relationship with the U.S. Oncology practices in Pittsfield, North Adams, and Great Barrington was highlighted by a November 10, 2004 recommendation letter written to Amgen's Steven Terreri by Fred Harrison, praising

Relator Kilcoyne's work. *See Exhibit D attached hereto.* In that letter, Mr. Harrison indicates that Relator Kilcoyne was "always welcome[] in [the U.S. Oncology] office."

120. Relator Kilcoyne delivered kickback checks to U.S. Oncology's Pittsfield, North Adams, and Great Barrington locations.

121. U.S. Oncology monitored all of the rebates and discounts delivered by Amgen to both it and its member practices. As discussed above, U.S. Oncology created and distributed a Quarterly Business Review that would explain to its member-practices what their anticipated rebates were, and where they were missing out on further opportunities to make extra money.

122. To guarantee its greatest profit, Ms. Radford explained that the practices owned and operated by U.S. Oncology had to "follow the . . . formulary" or the "standard of care" U.S. Oncology dictated, which included using the specific pharmaceuticals U.S. Oncology directed. These pharmaceuticals were, of course, the ones U.S. Oncology had negotiated kickbacks for using.

123. As noted above, in addition to the nearly 500 practices U.S. Oncology owned and operated during all times relevant to this complaint, U.S. Oncology offered a service model to independent practices, whereby U.S. Oncology would act as an administrator and adviser to the practice without actually owning it.

124. For these affiliated practices, U.S. Oncology would offer access to U.S. Oncology programming and, among other things, access to its contracting services and negotiated discounts and rebates. U.S. Oncology would market this as offering practice management assistance.

125. Ms. Radford explained that while U.S. Oncology could not tell these approximately 200 affiliated practices exactly what to do, they worked to convince them to adhere to the same formularies that the U.S. Oncology-owned practices used. U.S. Oncology used its service contracts to “persuade” these practices to use its formularies, as doing so would generate greater profits for U.S. Oncology.

126. George Lorenz, a former Regional Manager at Amgen responsible for the region spanning from Maine to Virginia, worked intimately with U.S. Oncology and its practices. On several occasions in or around 2004, Mr. Lorenz met with Relator Piacentile and shared his knowledge of the ongoing scheme. Mr. Lorenz’s statements directly support Ms. Radford’s allegations.

127. While Mr. Lorenz was working for Amgen, U.S. Oncology made him sign a contract allowing U.S. Oncology to profit by making “25%” on Amgen products. In short, Mr. Lorenz noted that the contract required Amgen to discount the drug to U.S. Oncology in exchange for U.S. Oncology “putting it on their formulary[,]” (*i.e.* telling physicians in its network to prescribe Amgen drugs).

128. The discounts provided were tied to “market share” and “volume” meaning that the more Amgen product purchased by U.S. Oncology and its practices, the better the discount. These discounts, of course, were not reported to or passed on to the Government or the named States in violation of state and federal law, as discussed herein.

129. Mr. Lorenz, like Ms. Radford, confirmed that the U.S. Oncology/Amgen agreement required U.S. Oncology to purchase a certain amount of Amgen product. In order to ensure compliance, Amgen would internally track and monitor U.S. Oncology’s

purchasing. If U.S. Oncology hit its purchasing mark, Amgen would issue checks to U.S. Oncology and also to the U.S. Oncology practices.

130. The kickback deal was negotiated by executives at both Amgen and U.S. Oncology. Amgen was represented by Vice President Bob Siegert and Mike Gouvia, a Vice President at U.S. Oncology was involved from U.S. Oncology's side.

131. The result of this contract was more than \$250 million per year of business from U.S. Oncology to Amgen.

132. Mr. Lorenz understood that U.S. Oncology would contract with Amgen for various rebates and discounts. Ms. Radford confirmed that U.S. Oncology would receive those monies from Amgen on a quarterly basis.

133. U.S. Oncology would then pass some of the discounts it received from Amgen on to its individual practices.

134. These payments would be made via quarterly rebate check from U.S. Oncology to the individual practices. Ms. Radford explained that these checks often "substantially" exceeded \$50,000 each.

135. Mr. Lorenz indicated that U.S. Oncology would skim a percentage of those payments before passing the remainder to the individual practices.

136. In addition to the payments made by Amgen to U.S. Oncology, Amgen would also send checks directly to the U.S. Oncology practices.

137. Relator Kilcoyne, one of the top selling Amgen sales representatives located in the Greater Worcester/Boston Area (Massachusetts), personally delivered these checks to U.S. Oncology practices in his service area. According to Relator

Kilcoyne, at times, these checks were for hundreds of thousands of dollars and were hotly anticipated by the physicians.

138. For example, Relator Kilcoyne recalls hand delivering particularly large kickback checks—valuing in the hundreds of thousands of dollars—to the U.S. Oncology affiliated practice located in Pittsfield, Massachusetts.

139. Amgen demanded that the deal with U.S. Oncology involve “split payments” because Amgen believed that making payments directly to the physicians would help to “motivate” the doctors to use Amgen products.

140. To enhance the likelihood that U.S. Oncology and its practices would continue to use Amgen product, Mr. Lorenz and others would often visit U.S. Oncology practices to check-up on their prescribing habits. These meetings often involved Mr. Lorenz meeting with the individual U.S. Oncology practices’ “business manager” who was largely responsible for placing purchase orders, informing the physicians of the various contracts between Amgen and U.S. Oncology, and managing how the physicians were prescribing.

141. To the extent Amgen concluded that U.S. Oncology or one of its practices was not meeting its purchasing volume requirement, Amgen would send a representative to explain the deficiency to U.S. Oncology and the practice, and help coach them into compliance. That person was usually from the corporate account executive side of Amgen.

142. Amgen would categorize the payments made to U.S. Oncology and its practices as both rebates and discounts.

143. U.S. Oncology would meet its Amgen quotas by placing a pharmacist of its choosing into the U.S. Oncology practices to help the practice obtain better pricing, track usage, and coach prescribing of on-formulary drugs.

144. In addition to forcing the U.S. Oncology practices it owned to use Amgen drugs, and in addition to heavily persuading the non-owned U.S. Oncology practices to use the same formulary, U.S. Oncology would also purchase Amgen drugs on its own (if it needed to) to help meet its volume requirement.

145. This would occur, in part, with a program at U.S. Oncology that Ms. Radford described as the “Merlin Project.”

146. Presently, the U.S. Oncology network includes a pharmaceutical distribution business currently distributing \$2.5 billion annually in oncology pharmaceuticals.

147. U.S. Oncology advertises that its reimbursement expertise helps providers, payers and pharmaceutical manufacturers realize cost efficiency and predictability in a largely unpredictable field of medicine. The facts, however, show U.S. Oncology used its expertise to defraud the Government.

148. During the billing cycles ending September 30, 2010 and 2009, 78.5% and 80.7% of U.S. Oncology’s revenue, respectively, was derived from comprehensive strategic alliances. The change from the prior year reflects the growth of physicians affiliated under targeted arrangements.

149. In late 2004, U.S. Oncology changed its model, no longer giving direct rebates to physicians. Instead, U.S. Oncology provided “prebates” which were built into the drug purchase price the U.S. Oncology physicians were paying. Ms. Radford

explained that U.S. Oncology was simply increasing the drug price and would keep portions of that inflated price as its profit.

150. Under the new model, U.S. Oncology was inflating the prices of the drugs it had the greatest discount from the manufacturer on, specifically, drugs from Amgen and Aventis.

151. Under guidelines promulgated by the U.S. Department of Health and Human Services, a pharmaceutical manufacturer must take affirmative steps to inform its customers of their obligation to accurately bill Medicare, and also must take affirmative steps to ascertain the manner in which its customers actually bill. *See OIG Guidance*, 68 Fed. Reg. at 23735.

152. Amgen had no guidelines regarding reporting of discounts posted among the billing information for clinics provided on its website. Information guidelines provided to its employees discussed the dangers under the AKS of providing financial incentives to customers, but did not prohibit its employees from doing so. Instead, the guidelines instructed employees to consult first with the legal department.

ii. Marketing the Spread

153. Amgen would show all practices, including U.S. Oncology practices, a “Net Cost Calculator[,]” which was a tool used by Amgen to indicate to physicians how much money they would be receiving in discounts, rebates, and other kickbacks. *See Exhibit E attached hereto.*

154. Using this Net Cost Calculator and other tools, Amgen would inform U.S. Oncology practices and physicians of the “spread” between the price U.S. Oncology was actually purchasing Amgen’s drugs for (minus all relevant kickbacks), and what those

same practices were receiving in reimbursements from the Government. As such, U.S. Oncology had complete knowledge throughout the relevant time period of the fact that it was receiving a pricing benefit from Amgen that was not being reported to the Government, so as to allow U.S. Oncology to profit from the difference between what it was paying for drugs from Amgen, and what it was receiving in reimbursements for those drugs from the Government.

155. Had the Government been aware of this “spread” that was the result of U.S. Oncology soliciting and accepting illegal kickbacks and pricing discounts from Amgen, such that Government “best price” rules and regulations were being violated, U.S. Oncology and Amgen, as co-conspirators, would have been liable to the Government for potentially hundreds-of-millions-of-dollars as a result of these best price violations.

156. Knowing that their scheme was illegal, U.S. Oncology and Amgen agreed to keep the Net Cost Calculator secret, not allowing any Amgen sales representatives to leave print copies of it with U.S. Oncology’s offices. As the Net Cost Calculator was a roadmap to how Amgen and U.S. Oncology would defraud the Government, both parties knew that the document was too sensitive to allow it to fall into the hands of the Government.

157. Knowing that this practice was improper and potentially illegal, Relator Kilcoyne refused to use the Net Cost Calculator in his presentation to U.S. Oncology physicians and practices, despite instructions to do so from his Amgen supervisors. This ultimately led to his termination from Amgen.

iii. Inflated “Data Fees”

158. U.S. Oncology also negotiated for and collected inflated “data fees” from pharmaceutical manufacturers it purchased drugs from, including Amgen. U.S. Oncology sought these fees as a way to increase its profitability while not having to report these monies to the Government.

159. According to Michael Louviere, Vice President of Marketing for U.S. Oncology, when U.S. Oncology received a rebate below the federal best price level, it ran the risk of having to have it “paid back[,]” and that in order to avoid that risk, U.S. Oncology demanded Amgen “throw in data fees and other stuff like that” instead of including those monies “in the rebate.”

160. Mr. Louviere explained that the data fees charged by U.S. Oncology were not set in advance by contract and were not disclosed to the Government.

161. Anthony Corrao, a former Amgen sales executive who managed Amgen’s negotiations with U.S. Oncology, admitted to Dr. Piacentile that in one year he paid U.S. Oncology over \$5 million in purported “data fees.” Mr. Corrao stated that executives at Amgen knew, as did he, that such payments were “bogus” and “wrong,” but paid them anyway at U.S. Oncology’s behest, as doing so would induce continued use of Amgen products.

162. For the years 2000 to 2002, U.S. Oncology collected data fees from 3 percent to as much as 6 percent of the total volume of drugs purchased by U.S. Oncology on behalf of its network physicians, although the actual cost of collecting data is only approximately one half of one percent of the purchase price.

163. The data fees collected by U.S. Oncology were grossly inflated in relationship to the work performed by U.S. Oncology. Although the fee ostensibly was to pay for the cost of collecting and reporting data for the manufacturer, the fee was tied to the market share of the drug that U.S. Oncology purchased.

164. The inflated data fees collected by U.S. Oncology from Amgen were not reported to the Government. Moreover, the Department of Health and Human Services Office of Inspector General has stated that although purchasers may contract in advance with manufacturers to collect data for a fee, the fee “should be fair market value for legitimate, reasonable and necessary services” and should be disclosed to the Government. *See* OIG Guidance, 68 Fed. Reg. at 23736.

iv. Free “Practice Management”

165. According to George Lorenz, one of Amgen’s pharmaceutical district sales directors, Amgen routinely supplied money, free services and equipment to U.S. Oncology affiliated physicians who prescribed Amgen drugs.

166. For instance, at U.S. Oncology’s behest, Amgen provided free practice management consulting services to certain U.S. Oncology physicians who prescribed Amgen drugs. The provision of these extraordinarily valuable services, to specific, targeted physicians by Amgen constituted illegal kickbacks.

167. Mr. Lorenz also disclosed to Relator Piacentile that Amgen gave physicians equipment including computers used to operate prescription inventory management software as an incentive to purchase Amgen drugs.

v. **Educational Grants**

168. In detailing Amgen’s marketing of its cancer drug Aranesp®, Mr. Lorenz described to Dr. Piacentile how Amgen tailored the grants it provided to physicians as rewards for purchasing this drug—not for legitimate research purposes. Relator Kilcoyne also understood that Amgen would use its grant money to reward market share movement of Amgen drugs.

169. Moreover, these grants were initiated and directed by Amgen’s sales and marketing agents rather than its science division.

170. To further entice the physicians’ use of Amgen products, Amgen would send directly to the U.S. Oncology physicians’ various “educational grants.”

171. For example, Mr. Lorenz shared that Amgen provided educational grants to a U.S. Oncology owned practice in Berkshire (Pittsfield), Massachusetts, which Relator Kilcoyne serviced and which had a good reputation for strong market share movement on Amgen product. Specifically, the U.S. Oncology Berkshire practice moved its market share to 92% usage of Amgen’s Aranesp® drug. Mr. Lorenz stated that the U.S. Oncology Berkshire practice, with good usage metrics for Amgen’s products, would receive more educational monies than other lesser performing U.S. Oncology practices.

172. These educational grants were knowingly accepted by U.S. Oncology physicians as a form of kickback in exchange for their high usage of Amgen products, and were not properly reported to the Government.

vi. Speaker Fees

173. Dr. Piacentile interviewed Arthur Hodari Henry, an Amgen marketing representative, on June 6, 2004. Mr. Henry detailed Amgen's efforts to market Aranesp®, Neupogen®, and Neulasta®. Amgen routinely paid "honoraria" and "speaking fees" to physicians and nurses who had authority to recommend pharmaceutical purchases. These fees typically amounted to \$1,000 to \$1,500 for each engagement. The fees were usually given as a reward to physicians who prescribed a satisfactory quota of Amgen drugs.

174. U.S. Oncology physicians often received such speaking fees from Amgen.

175. For example, Amgen paid \$5,000 in fees to William Faines, a pharmacy director for Defendant U.S. Oncology, to talk to doctors about the effectiveness of Amgen drugs.

176. Amgen also paid honoraria to another U.S. Oncology individual named Julie out of North Carolina for various speaking engagements, largely because of her practice's enhanced usage of Amgen products.

177. Amgen paid honoraria to physicians out of Amgen's educational budget. Lavish dinners which accompanied such talks were paid for from Amgen's promotional budget.

178. These speaker fees were knowingly accepted by U.S. Oncology personnel as a form of kickback in exchange for their high usage of Amgen products, and were not properly reported to the Government.

vii. Travel Offers

179. Relator Kilcoyne has personal knowledge that Amgen also offered, and U.S. Oncology affiliated physicians accepted, travel packages whereby for the purported purpose of educational meetings wherein lip service would be paid to teaching U.S. Oncology physicians about Amgen's products, Amgen would offer U.S. Oncology physicians expensive trips to luxury hotels—such as the Hotel Viking in Newport, Rhode Island—as a form of kickback in exchange for U.S. Oncology's continued use of Amgen's products.

180. These travel offers were knowingly accepted by U.S. Oncology physicians as a form of kickback in exchange for their high usage of Amgen products, and were not properly reported to the Government.

viii. Additional Rebates and Discounts

181. Mr. Louviere explained that in addition to the discounts, data fees, and other kickbacks discussed above, U.S. Oncology negotiated for and received an additional \$30 million “rebate” in 2003 from Amgen.

182. Specifically, U.S. Oncology negotiated enhanced Aranesp discounts and rebates by which it received an additional 5% off-invoice discount for a total of 10% off WAP through September 2002, plus an additional 5% rebate.

183. U.S. Oncology purposefully chose not to report this \$30 million “rebate” from Amgen to the Government.

B. Illegality of U.S. Oncology's Fraud

184. The value of defendant U.S. Oncology's illegal collections is the measure of the kickbacks or price discounts received by U.S. Oncology and its physicians, plus the unnecessary reimbursement paid by the government-funded health benefit programs.

185. Defendant U.S. Oncology knowingly engaged in the fraudulent conduct described in this Fourth Amended Complaint for the purpose of enriching itself and obtaining increased physician contracts at the expense of the federal and state governments. In particular, through the use of the Quarterly Business Review which detailed incentive payments (*i.e.*, illegal kickbacks) from manufacturers, U.S. Oncology encouraged all of its network physicians to actively engage in moving market share to manufacturers who provided greater "incentives". Rather than focusing on using the pharmaceutical products that offered the best results for its cancer patients, U.S. Oncology's primary motivation was procuring the largest kickbacks possible.

186. By facilitating kickbacks to physicians, defendant U.S. Oncology violated applicable statutes and regulations, including the AKS, the FCA, and the Medicaid Rebate Statute. Moreover, U.S. Oncology violated the best price statute.

187. Michael Louviere, Vice President of Marketing for U.S. Oncology, outright admitted to Relator Piacentile that U.S. Oncology knew that its arrangement with Amgen was violating best price rules and regulations. Mr. Louviere said that "**we do dip below [best price] every now and then and what happens if they catch us then they . . . will have to go back and pay back the government[.]**" Mr. Louviere indicated that it was "worth the chance" and that having to make back-payments was "no big deal[.]"

188. Through its illegal business practices, defendant U.S. Oncology encouraged overutilization of potentially unnecessary prescription drugs, induced excessive payments from federal and state government-funded health benefit programs, undermined physicians' and patients' freedom to choose appropriate drug therapies, and generated additional income through referrals received.

189. The Government's prosecution of other companies including Amgen and Amerisource Bergen shows that it believed this misconduct was material to its decision to reimburse physician-payments. Had federal and state government-funded health benefit programs been aware that drugs were prescribed by U.S. Oncology-network physicians had resulted from the conduct alleged in this Fourth Amended Complaint, they would not have paid the claims submitted as a result of U.S. Oncology's illegal acts.

190. Knowing the consequences of discovery of the fraudulent scheme, U.S. Oncology concealed its illegal activities from the Government in order to continue defrauding federal and state government-funded health insurance programs.

191. For example, U.S. Oncology knowingly refused to disclose to federal and state governments the rebates and data fees it received from manufacturers like Amgen. Amgen and U.S. Oncology, as co-conspirators, submitted false pricing data to the Government to encourage inflated reimbursement to prescribers, to avoid paying higher Medicaid rebates, and to conceal their illegal activities from the Government. As a result, federal and state government-funded health insurance programs paid hundreds-of millions-of-dollars in reimbursements for Amgen prescription drugs that were prescribed by U.S. Oncology affiliated physicians, in part, because of the payment of unlawful kickbacks by Amgen.

192. As a result of U.S. Oncology's unlawful behavior, the Government has suffered substantial economic harm. Relators estimate U.S. Oncology improperly received in excess of \$500 million due to its kickback scheme, and an additional \$500 million due to its best price conspiracy.

GENERAL ALLEGATIONS

A. Federal Government-Funded Health Assistance Programs and Direct Health Insurance Plans

1. Medicare

a. Generally

193. The Medicare Program is a federal government-funded medical assistance program, primarily benefiting the elderly, that was created in 1965 when Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (hereinafter, "Medicare"). Medicare is administered by the federal Centers for Medicare and Medicaid Services ("CMS"), known prior to 2001 as the Health Care Financing Administration, which is a division of the U.S. Department of Health and Human Services ("HHS"). It is funded by taxpayer revenue. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services, and durable medical equipment to persons older than 65 years of age and others who qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment for certain prescription medications used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with end-stage renal disease and/or undergoing dialysis. Pursuant to the Medicare Prescription Drug Improvement and

Modernization Act of 2003, Medicare Part D took effect, extending prescription drug coverage to all Medicare-eligible persons who elect to participate in Part D.

b. "Reasonable and Necessary" Precondition to Payment

194. Under Medicare, reimbursement is prohibited if the item or service is not "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

2. Medicaid

195. The Medicaid Program (hereinafter, "Medicaid") was also created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the needy, medically-needy aged, blind, or disabled, and needy families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both federal and state government (collectively referred to as "Medicaid Funds"), with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b, 1396d(b). At the federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a state Medicaid agency to administer the program. Medicaid was designed to assist participating states in providing medical services, durable medical equipment, and prescription drugs to financially-needy individuals who qualify for Medicaid.

196. Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the HHS. Among other forms of medical assistance, the states are permitted to provide medical assistance from the Medicaid Funds to eligible persons for inpatient and outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A), 1396d(a)(12).

3. General Provisions Applicable to Both Medicare and Medicaid

197. Federal law prohibits a person from knowingly presenting or causing to be presented to Medicare or Medicaid a claim for a medical or other item or service that the person knows or should know was “not provided as claimed,” a claim for such items or services that is “false or fraudulent,” or a claim that is “for a pattern of medical or other items or services that [the] person knows or should know are not medically necessary.” 42 U.S.C. §§ 1320a-7a(a)(1)(A), (B) & (E). Violation of this section is subject to a civil monetary penalty of \$10,000 for each item or service, plus damages measured as three times the amount of each claim submitted, and exclusion from further participation in the programs.

4. Direct Federal Health Insurance Plans

a. TRICARE/CHAMPVA

198. TRICARE, originally known as the Civilian Health and Medical Program of the Uniformed Services, 10 U.S.C. §§ 1071-1106, administered by the Department of Defense (“DoD”), is the United States military’s managed health care program, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents.

199. TRICARE operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits. Five managed care support contractors create networks of civilian health

care providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

200. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), administered by the Department of Veterans Affairs (the "VA"), provides healthcare coverage to qualified families of deceased or 100% disabled veterans.

b. FEHBP

201. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for nearly 8.7 million federal employees, retirees, and their dependents. The FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

B. The Anti-Kickback Statute, Kickback Regulations and Compliance Guides, the False Claims Act, and the Medicaid Rebate Statute

a. The Anti-Kickback Statute

202. The Anti-Kickback Statute prohibits kickbacks by providing a civil monetary penalty of \$50,000 for each act by an individual or entity that violates 42 U.S.C. § 1320a-7a(a)(7), which defines "[i]mproperly filed claims" as "[a]ny person (including an organization, agency, or other entity . . .) that . . . commits an act described in paragraph (1) or (2) of section" 1320a-7b(b) of this title. [defining the criminal offense of "illegal remuneration" (*i.e.*, kickbacks)]. The statute defines "illegal remuneration" (*i.e.*, kickbacks) as:

(1) Whoever knowingly and willfully *solicits or receives* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –

* * *

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

* * *

(2) Whoever knowingly and willfully *offers or pays* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

* * *

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

42 U.S.C. § 1320a-7b(b) (emphasis added). The offense is also a felony punishable by fines of up to \$25,000 and imprisonment for up to five years. 42 U.S.C. § 1320a-7b(b).

203. The Anti-Kickback Statute also prohibits inducements to patients (*i.e.* coupons) by providing civil penalties of \$10,000 for each item or service by an individual or entity that violates 42 U.S.C. § 1320a-7a(a)(5), which defines “[i]mproperly filed claims” as “[a]ny person (including an organization, agency, or other entity . . .) that --

(5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section 1320a-7(h) of this title) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under subchapter XVIII of this chapter, or a State health care program (as so defined)[.]

42 U.S.C. § 1320a-7a(a)(5).

204. In accordance with the Anti-Kickback Statute, Medicare and Medicaid regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals that takes into account the “volume or value” of any referrals or business generated. *See 42 C.F.R. § 1001.952(f)(2)*. Such remuneration amounts to a kickback and can increase the expenditures paid by government-funded health benefit programs by leading to over-utilization of prescription drugs, inducing medically unnecessary and excessive reimbursements. Kickbacks also effectively reduce patients’ healthcare choices, because unscrupulous (or unknowing) physicians steer their patients to various drug products based on the physician’s own interests rather than the patients’ medical needs.

205. The Anti-Kickback Statute contains statutory exceptions and regulatory “safe harbors” excluding certain types of conduct from liability. *See 42 U.S.C. § 1320a-7(b)(3) and 42 C.F.R. § 1001.952*. None of these statutory exceptions or regulatory safe harbors applies to U.S. Oncology’s conduct in this matter.

206. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended that Act to impose an administrative civil monetary penalty for Anti-Kickback Statute violations: \$50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such

remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

b. Kickback Regulations and Compliance Guides

207. American Medical Association (“AMA”) policy states that “[t]o avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

- (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. . . . Cash payments should not be accepted.
- (2) Individual gifts ~~of minimal~~ value are permissible as long as the gifts are related to the physician’s work (e.g., pens and notepads).

* * *

- (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician’s prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

American Medical Association, Council on Ethical and Judicial Affairs, “Gifts to Physicians from Industry” *See* AMA Ethical Opinion 8.061.

208. AMA policy also prohibits physicians from accepting “any kind of payment or compensation from a drug company . . . for prescribing its products.” *See* AMA Ethical Opinions 6.04 (Fee Splitting); *see also* AMA Ethical Opinion 6.02 (Fee Splitting).

209. The American College of Physicians’ Ethics Manual (“Ethics Manual”) recognizes “drug industry gifts” as having potentially negative influence on clinical

judgment and notes that it is “unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells . . . medications that are used in the care of the physician’s patients.” *See Ethics Manual, Financial Conflicts of Interest.*

210. Free or discounted equipment or services, such as computers, faxes or business management consulting services to physicians are “suspect” under the Anti-Kickback Statute, 42 U.S.C. §1320(a), *et seq.*, as are educational grants and payments to physicians for consulting services. *See Office of Inspector General Guidance, COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS*, 68 Fed. Reg. 86 at 23731) (hereinafter, “OIG Guidance.”)

211. Research contracts that originate through the sales and marketing functions—or that are offered to doctors in connection with sales contacts—are particularly suspect under the Anti-Kickback Statute. *See OIG Guidance*, 68 Fed. Reg. at 23738. Most dubious in this regard is research that is initiated or directed by the sales or marketing agents that is not transmitted to the manufacturer’s science division. *Id.*

212. Free or discounted equipment or services, such as computers, faxes, or business management consulting services are “suspect” under the Anti-Kickback Statute. *See* 59 Fed. Reg. at 65376.

c. The False Claims Act

213. Originally enacted in 1863, the Federal False Claims Act (the “FCA”), 31 U.S.C. §§ 3729, *et seq.*, was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government’s ability to recover

losses sustained as a result of fraud against the United States. Further clarifying amendments were adopted in May 2009.

214. The FCA imposes liability upon any person who “knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval”; or “knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim”; or “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(A), (B), (G). Any person found to have violated these provisions is liable for a civil penalty of up to \$11,000 (adjusted annually for inflation) for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

215. The Act empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action. 31 U.S.C. § 3730(b).

216. Significantly, the FCA imposes liability where the conduct is merely “in reckless disregard of the truth or falsity of the information,” and further clarifies that “no proof of specific intent to defraud is required.” 31 U.S.C. § 3729(b).

217. The FCA also broadly defines a “claim” as one that includes “any request or demand, whether under a contract or otherwise, for money or property . . . that . . . is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.” 31 U.S.C. § 3729(b)(2)(A).

218. The FCA is violated where a person who receives or provides kickbacks or price discounts in connection with the purchase or sale of a reimbursable drug seeks reimbursement from a federal government-funded health insurance program for the drug and certifies compliance with the Anti-Kickback Statute or the Medicaid Rebate Statute.

d. The Medicaid Rebate Statute

219. The Medicaid Rebate Statute, 42 U.S.C. §1396r-8, is designed to return money to the Medicaid program in the form of rebates from drug manufacturers.

220. In order to have their drugs eligible for Medicaid payment, all drug manufacturers must provide “best price” information to the CMS. The CMS uses this “best price” information to calculate rebates payable to the Medicaid program.

221. Drug manufacturers provide both “best price” information and Average Manufacturer Price information to CMS. CMS then calculates a unit rebate amount, and provides that information to state Medicaid agencies. The states then use utilization data provided by pharmacies, and the unit rebate amount, to calculate the rebate owed to them by the manufacturer. The entire system, however, is based upon manufacturers honestly

conveying to CMS correct “best price” information and Average Manufacturer Price information. Any errors, intentional or unintentional, will cause an underpayment in rebate amounts.

222. The Medicaid Rebate Statute states in part: the term “best price” - shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). *See* 42 U.S.C.1396r-8(c)(1)(c)(ii).

223. The federal government has great financial interest in the program. The Statute provides that amounts received by the states under the “best prices” program “shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of” calculating the federal contribution to state Medicaid programs. *See* 42 U.S.C. 1396r-8(b)(1)(B).

224. As result of pervasive “best price” fraud, the Office of Inspector General promulgated compliance materials on April 28, 2003 which observed that manufacturers have “a strong financial incentive to hide de facto pricing concessions” (in particular, kickbacks and price discounts) that could affect “best price” calculations and trigger increased Medicaid rebates. *See* OIG Guidance, 68 Fed. Reg. at 23735. Moreover, the Office of Inspector General instructed manufacturers to report “best prices” which “accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.” *Id.* at 23733-23734. In sum, according to the Office of Inspector General,

“pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.” *Id.* at 23734.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1) (1994))
(Pre-May 20, 2009 Conduct)

225. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

226. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1)(A) (2009))
(Post-May 20, 2009 Conduct)

227. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between

Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

228. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(2) (1994))
(Pre-June 7, 2008 Conduct)

229. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

230. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants have knowingly made, used, or caused to be made or used false records or statements – i.e., the false certifications and representations made or caused to be made by defendants – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(2).

FOURTH CAUSE OF ACTION

(False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(1)(B) (2009))
(Post-June 7, 2008 Conduct)

231. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

232. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants have knowingly made, used, or caused to be made or used false records or statements – i.e., the false certifications and representations made or caused to be made by defendants – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

FIFTH CAUSE OF ACTION

(False Claims Act: Making or Using False Record
Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(7) (1994))
(Pre-May 20, 2009 Conduct)

233. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between

Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

234. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants knowingly made, used or caused to be made or used false records or false statements—*i.e.*, the false certifications made or caused to be made by defendants—material to an obligation to pay or transmit money to the Government or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the United States.

SIXTH CAUSE OF ACTION

(False Claims Act: Making or Using False Record
Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(1)(G) (2009))
(Post-May 20, 2009 Conduct)

235. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

236. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants knowingly made, used or caused to be made or used false records or false statements—*i.e.*, the false certifications made or caused to be made by defendants—material to an obligation to pay or transmit money to the Government or

knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the United States.

SEVENTH CAUSE OF ACTION

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(3))
(Pre-May 20, 2009 Conduct)

237. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if full set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

238. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants conspired to get false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims by the United States.

EIGHTH CAUSE OF ACTION

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(1)(C))
(Post-May 20, 2009 Conduct)

239. Relators repeat and incorporate by reference the allegations contained in Paragraphs 1 through 223 of this Complaint as if full set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between

Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

240. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants conspired to get false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims by the United States.

NINTH CAUSE OF ACTION

(California False Claims Act)
(Cal. Govt. Code §§ 12651 *et seq.*)

241. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

242. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

243. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

244. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

245. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

246. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TENTH CAUSE OF ACTION

(Florida False Claims Act)
(Fla. Stat. Ann. §§ 68.081 *et seq.*)

247. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology's conduct).

248. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

249. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

250. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

251. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

252. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

ELEVENTH CAUSE OF ACTION

(Hawaii False Claims Act)
(Haw. Rev. Stat. §§ 661-21 *et seq.*)

253. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology's conduct).

254. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

255. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

256. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

257. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

258. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWELFTH CAUSE OF ACTION

(Illinois Whistleblower Reward and Protection Act)
(740 Ill. Comp. Stat. §§ 175/1 *et seq.*)

259. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between

Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology's conduct).

260. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

261. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

262. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

263. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

264. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTEENTH CAUSE OF ACTION

(Louisiana Medical Assistance Programs Integrity Law)
(La. Rev. Stat. Ann. §§ 46:439.1 *et seq.*)

265. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the

facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

266. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

267. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

268. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

269. By reason of the Defendants’ acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

270. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FOURTEENTH CAUSE OF ACTION

(Massachusetts False Claims Law)
(Mass. Gen. Laws ch. 12, §§ 5A *et seq.*)

271. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct). Moreover, Paragraphs 32, 42, 111, 114, 137, 138, and 171 detail activities of U.S. Oncology occurring in, or specifically targeting, the State of Massachusetts.

272. Relator Kilcoyne was an Amgen sales representative for the Greater Worcester/Boston, Massachusetts area. Relator Kilcoyne specifically recalls delivering Amgen “rebate” checks to physicians at three Massachusetts-based U.S. Oncology practices in his service area. Relator Kilcoyne recalls these quarterly rebate checks being worth several hundred thousand dollars each.

273. As addressed above, Relator Kilcoyne called upon Berkshire Hematology Oncology, a U.S. Oncology practice with three locations within Massachusetts. Relator Kilcoyne specifically recalls delivering kickback checks to that practice.

274. Berkshire Hematology Oncology never reported these illicit kickback checks to the State of Massachusetts when submitting claims for payment to the government-run health care programs, including but not limited to, the Massachusetts Medicaid Program.

275. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

276. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

277. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

278. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

279. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FIFTEENTH CAUSE OF ACTION

(Michigan Medicaid False Claims Act)
(Mich. Comp. Laws §§ 400.601 *et seq.*)

280. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks

and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

281. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

282. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

283. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

284. By reason of the Defendants’ acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

285. Pursuant to Mich. Stat. § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud, three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SIXTEENTH CAUSE OF ACTION

(Nevada False Claims Act)
(Nev. Rev. Stat. §§ 357.010 *et seq.*)

286. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

287. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

288. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

289. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

290. By reason of the Defendants’ acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

291. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTEENTH CAUSE OF ACTION

(New Mexico Medicaid False Claims Act and Fraud Against Tax Payers Act)
(N.M. Stat. Ann. §§ 27-14-1 *et seq.* and §§ 44-9-1 *et seq.*)

292. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

293. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

294. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

295. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

296. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

297. Pursuant to N.M. Stat. Ann. § 27-14-4 and § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTEENTH CAUSE OF ACTION

(New York False Claims Act)
(N.Y. State Fin. Law §§ 187 *et seq.*)

298. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology's conduct).

299. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

300. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to

induce the New York State Government to approve and pay such false and fraudulent claims.

301. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

302. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Pursuant to N.Y. State Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of \$12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINETEENTH CAUSE OF ACTION

(Texas Medicaid Fraud Prevention Act)
(Tex. Hum. Res. Code §§ 36.001, *et seq.*)

303. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology's conduct). Moreover, Paragraphs 33–34 highlight that U.S. Oncology was headquartered, for all relevant times, in the State of Texas, and

Paragraph 81 alleges that U.S. Oncology operated a billing center—through which it directly facilitated the submission of false claims to the Government—in Houston, Texas.

304. U.S. Oncology, for all times relevant to this Fourth Amended Complaint, was headquartered in Houston, Texas. Following its \$2.2 billion acquisition by McKesson Corporation, U.S. Oncology is presently headquartered in The Woodlands, Texas.

305. U.S. Oncology also operated one of its regional billing centers in Texas.

306. The illegal kickback scheme and other related illegal conduct set forth above was part of U.S. Oncology’s main strategy for driving revenue and profits, and was known about, negotiated for, approved of, and promoted by executives at U.S. Oncology’s highest levels, include the corporate office in Texas.

307. Under the Texas Medicaid Fraud Prevention Act (“TMFPA”), an unlawful act subjects a defendant to liability for the value of payment related to the unlawful act.

308. There are thirteen unlawful acts specified in the TMFPA:

a. knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

b. knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

c. knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the

benefit or payment to a use other than for the benefit of the person on whose behalf it was received;

d. knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning: (A) the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as: (i) a hospital; (ii) a nursing facility or skilled nursing facility; (iii) a hospice; (iv) an ICF-IID; (v) an assisted living facility; or (vi) a home health agency; or (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

e. except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;

f. knowingly presents or causes to be presented a claim for payment under the Medicaid program for a product provided or a service rendered by a person who: (A) is not licensed to provide the product or render the service, if a license is required; or (B) is not licensed in the manner claimed;

g. knowingly makes or causes to be made a claim under the Medicaid program for: (A) a service or product that has not been approved or acquiesced in

by a treating physician or health care practitioner; (B) a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the health care industry; or (C) a product that has been adulterated, debased, mislabeled, or that is otherwise inappropriate;

h. makes a claim under the Medicaid program and knowingly fails to indicate the type of license and the identification number of the licensed health care provider who actually provided the service;

i. conspires to commit a violation of these enumerated acts;

j. is a managed care organization that contracts with the commission or other state agency to provide or arrange to provide health care benefits or services to individuals eligible under the Medicaid program and knowingly: (A) fails to provide to an individual a health care benefit or service that the organization is required to provide under the contract; (B) fails to provide to the commission or appropriate state agency information required to be provided by law, commission or agency rule, or contractual provision; or (C) engages in a fraudulent activity in connection with the enrollment of an individual eligible under the Medicaid program in the organization's managed care plan or in connection with marketing the organization's services to an individual eligible under the Medicaid program;

k. knowingly obstructs an investigation by the attorney general of an alleged unlawful act under this section;

1. knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program; or

m. knowingly engages in conduct that constitutes a violation under Section 32.039(b).

309. By virtue of the facts set forth above, Defendant committed unlawful acts as defined by the TMFPA, including, without limitation, the unlawful acts set forth at subsections (a), (b), (c), (d), (e), (i), (l), and (m) of the preceding paragraph.

310. By virtue of the facts described above, Defendant conspired to commit unlawful acts, in violation of the TMFPA.

311. Pursuant to Tex. Hum. Res. Code Ann. § 36.052, a person who commits an unlawful act is liable to the State of Texas for: (1) the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party; (2) interest on the amount of the payment or the value of the benefit described by Subdivision (1); (3) a civil penalty; and (4) two times the amount of the payment or the value of the benefit described by Subdivision (1).

312. Accordingly, the State of Texas is entitled to two times the amount of any payments obtained by the Defendants from the Texas Medicaid program as a result of Defendants' unlawful acts, along with appropriate interest and civil penalties.

TWENTIETH CAUSE OF ACTION

(Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. §§ 8.01-216.1 *et seq.*)

313. Relators repeat and incorporate by reference the allegations contained in paragraphs 1 through 223 of this Complaint as if fully set forth herein, particularly the facts alleged in Paragraphs 37–43 (relating to the solicitation and receipt of kickbacks and additional unlawful remuneration), 66–183 (details of the conspiracy between Amgen and U.S. Oncology and the various violations that resulted in the presentation and submission of false claims for payment to the Government), and 184–191 (a summary of the unlawfulness of U.S. Oncology’s conduct).

314. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia Commonwealth Government for payment or approval.

315. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia Commonwealth Government to approve and pay such false and fraudulent claims.

316. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

317. By reason of Defendants’ acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

318. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

DEMANDS FOR RELIEF

WHEREFORE, Relators, on behalf of the United States Government, demand judgment against Defendant U.S. Oncology, ordering that:

As to the Federal Claims:

- a. Defendant pay an amount equal to three times the amount of damages the United States Government has sustained because of defendant's actions which Relators currently estimate to be in the hundreds of millions of dollars, plus a civil penalty of not less than \$6,500 and not more than \$11,000 (adjusted for inflation), or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729, *et seq.*;
- b. Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;
- c. Relators be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law; and
- d. Relators be awarded such other and further relief as the Court may deem to be just and proper.

As to the State Claims:

- e. Relators and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a

result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants within each State, all as provided by:

Cal. Govt. Code 12651;
Fla. Stat. Ann. 68.082;
Haw. Rev. Stat. 661-21;
740 Ill. Comp. Stat. 175/3;
La. Rev. Stat. § 46:438.6;
Mass. Gen. Laws Ch. 12 5B;
Mich. Comp. Laws § 400.612;
Nev. Rev. Stat. Ann. 357.040;
N.M. Stat. Ann. § 27-14-4 and § 44-9-3;
N.Y. Fin. Law § 189.1(g); and
Va. Code Ann. 8.01-216.3.

f. Relators and Plaintiff State of Texas be awarded statutory damages in an amount equal to two times the amount of actual damages that Texas has sustained as a result of the defendants' actions within Texas, as well as the maximum statutory civil penalty for each violation of Tex. Hum. Res. Code Ann. 36.052;

g. Relators be awarded their relator's share of any judgment to the maximum amount provided pursuant to:

Cal. Govt. Code 12652(g)(2);
Fla. Stat. Ann. 68.085;
Haw. Rev. Stat. 661-27;
740 Ill. Comp. Stat. § 175/4(d);
La. Rev. Stat. § 46:439.4;
Mass. Gen. Laws Ch. 12 5F;
Mich. Comp. Laws § 400.610a;
Nev. Rev. Stat. Ann. § 357.210;
N.M. Stat. Ann. § 27-14-9 and § 44-9-7;
N.Y. State Fin. Law § 190.6;
Tex. Hum. Res. Code Ann. 36.110; and
Va. Code Ann. 8.01-216.7.

h. Relators be awarded all costs and expenses associated with each of the pendent State claims, plus attorney's fees as provided pursuant to:

Cal. Govt. Code 12652(g)(8);

Fla. Stat. Ann. 68.086;
Haw. Rev. Stat. 661-27;
740 Ill. Comp. Stat. § 175/4(d);
La. Rev. Stat. § 46:439.4;
Mass. Gen. Laws Ch. 12 5F;
Mich. Comp. Laws § 400.610a;
Nev. Rev. Stat. Ann. 357.180;
N.M. Stat. Ann. § 27-14-9 and § 44-9-7;
N.Y. State Fin. Law § 190.7;
Tex. Hum. Res. Code Ann. 36.110; and
Va. Code Ann. 8.01-216.7.

i. Relators and the State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

TRIAL BY JURY

Relators hereby demand a trial by jury as to all issues.

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Dated: November 16, 2018